UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

BRAINTREE LABORATORIES, INC., Plaintiff, v. BRECKENRIDGE PHARMACEUTICAL, INC., Defendant.	Civil Action No. 12-cv-6851-AJN ECF Case

DEFENDANT BRECKENRIDGE PHARMACEUTICAL, INC.'S REPLY TO PLAINTIFF BRAINTREE LABORATORIES, INC.'S OPPOSITION TO MOTION FOR SUMMARY JUDGMENT OF NONINFRINGEMENT

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes

I. INTRODUCTION

Breckenridge's motion involves one simple question: if Breckenridge's ANDA is approved by the FDA, will Breckenridge market a product having a volume of "about 100 ml to about 500 ml?" The answer is no. Like SUPREP®, Breckenridge's ANDA Product is a ***two-bottle kit*** for which the FDA-approved label ***requires*** a patient to ingest a total of ***946 ml*** of aqueous solution. Breckenridge's ANDA does not seek approval of a label that suggests or permits a patient to consume a total dosage less than 946 ml for any reason. These undisputed facts mandate a finding of noninfringement because the product defined by Breckenridge's ANDA does not meet the "about 100 ml to about 500 ml" volume limitation present in every asserted claim of Braintree's '149 patent. Infringement cannot be found where, as here, an ANDA seeks FDA approval of a drug or use that is different from that claimed in the asserted patent. *See* 35 U.S.C. § 271(e)(2)(A); *Allergan, Inc. v. Alcon Labs., Inc.*, 324 F.3d 1322, 1332 (Fed. Cir. 2003); *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1356 (Fed. Cir. 2003).

Breckenridge's noninfringement argument is fundamentally different from that presented by Novel Laboratories, Inc. at the Federal Circuit. Novel argued that "purgation" meant "cleansing," and that one bottle (half the full dose) would not achieve a full "cleansing" and thus would not infringe. *Braintree Labs., Inc. v. Novel Labs., Inc.*, 749 F.3d 1349, 1354 (Fed. Cir. 2014); *see* Dkt. 86-17 at 1-2 (Novel Statement of the Issues on Appeal). Novel's construction of the term "purgation" was rejected by the Federal Circuit. Since purgation does not mean a full cleansing, one bottle can result in purgation. ***But Novel did not argue*** in its briefs that administration of a single (473 ml) bottle of the ANDA Product is an off-label use, nor did it explain that— regardless of the definition of "purgation"—the "about 100 ml to 500 ml" claim limitation limits the total volume of solution ingested by a patient. Braintree admits that Novel *waived* those arguments. *See* Dkt. 68 at 3; Dkt. 86-18 at 3-4.

The Federal Circuit majority's statement that "Braintree's 'one bottle' infringement theory . . . can prevail" specifically and only addressed Novel's argument that if "purgation" meant "cleansing," then it took two bottles to "cleanse" the colon. *See* 749 F.3d at 1354 (making the statement under the headings "Claim Construction"; "Purgation"). This is *not* the defense that Breckenridge has raised. With respect to Breckenridge's defense, the Federal Circuit majority opinion contains no analysis or holding as to whether, under *Warner-Lambert* and its progeny, the properly-defined ANDA Product is 946 ml and therefore cannot infringe Braintree's claims to a composition having a volume of "about 100 ml to about 500 ml." Judge Dyk's *sua sponte* dissent does not create a holding of the majority on this issue.[1] Braintree's attempt to avoid all judicial review of this issue based on Novel's waiver should be rejected. *See, e.g., Parklane Hosiery Co. v. Shore*, 439 U.S. 322, 327 n.7 (1979) ("It is a violation of due process for a judgment to be binding on a litigant who was not a party or a privy and therefore has never had an opportunity to be heard.").

Braintree's infringement arguments improperly divide the ANDA Product and rely on an untenable approach that renders the "about 100 ml to about 500 ml" limitation meaningless. Breckenridge's Motion for Summary Judgment should be granted on the merits.

II. ARGUMENT

The proposed labeling for Breckenridge's ANDA Product, the controlling case law, and the plain language of the claims, viewed in light of the specification and the prosecution history, all demonstrate that a ***single bottle*** of Breckenridge's ANDA Product cannot be the basis for a finding of infringement.

[1] Braintree cites no authority for its assertion that Novel's waiver is "irrelevant" because the argument was raised in a dissent that the majority did not adopt. Opp. at 9. Courts routinely apply waiver where a party fails to raise an issue, leaving the matter open for future litigants to raise. *See, e.g., Argentina v. NML Capital, Ltd.*, 134 S. Ct. 2250, 2255 n.2 (2014) (electing to "assume without deciding" the scope of Rule 69 where the petitioner forfeited the argument by raising it for the first time in its reply brief at the Supreme Court).

A. Under the Hatch-Waxman Act, the Breckenridge ANDA Product Cannot Be Administered as a 473 ml Solution for Inducing Purgation

While Braintree is correct that infringement in a Hatch-Waxman case "is determined by traditional patent infringement analysis," *Warner-Lambert*, 316 F.3d at 1365, Braintree mistakenly concludes that an infringement analysis under § 271(e) can ignore how the product is defined by an ANDA applicant's proposed label, *see* Opp. at 18-19. In *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1569-70 (Fed. Cir. 1997), the Federal Circuit rejected a patentee's argument that the *mere filing* of an ANDA proves infringement under § 271(e)(2)(A), but held that the Hatch-Waxman infringement inquiry is "properly grounded in the ANDA application and the extensive materials typically submitted in its support." Because the ANDA defines the drug product that will be sold upon FDA approval, the determination of infringement in an ANDA case is made based on what will be the on-label use of the drug product as a whole once it is approved. *Bayer Schering Pharma AG v. Lupin, Ltd.*, 676 F.3d 1316, 1325 (Fed. Cir. 2012); *Warner-Lambert Co.*, 316 F.3d at 1364-65; *Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1250 (Fed. Cir. 2000).

An ANDA product cannot differ from the approved reference drug in "route of administration, ***dosage form***, or ***strength***" unless the generic obtains special permission from the FDA, which Breckenridge has not done here. 21 U.S.C. § 355(j)(2)(C) (emphasis added). It is undisputed that SUPREP is a ***two-bottle*** kit, and the FDA-approved label ***requires*** a patient to take ***both bottles*** of diluted solution over the course of an administration period.[2] MF ¶7, SF33. [3] Like SUPREP, the Breckenridge product requires ingestion of 946 ml of aqueous solution as the

[2] Contrary to Braintree's curious argument, there is no "bizarre scenario" where the determination of infringement under § 271(e)(2) is inconsistent with the determination under § 271(a), because upon approval, Breckenridge's product labeling will carry this same requirement. Opp. at 19 n.20.

[3] Citations to SF refer to the parties' Stipulated Facts. Dkt. 86-20. Citations to "MF" refer to Breckenridge's Rule 56.1 Statement, including Braintree's Counterstatement. *See* Dkt. 94. Citations to "BMF" refer to Braintree's Rule 56.1 Statement, including Breckenridge's Counterstatement, filed herewith.

only FDA-approved dosage for the only FDA-approved indication: "cleansing the colon in preparation for colonoscopy." SF4, SF33. The '149 patent does not claim this FDA-approved indication or dosage; rather, it claims a composition "for inducing purgation" that is only "about 100 ml to about 500 ml" in volume. Braintree's argument that each single bottle of the ANDA Product infringes the claims improperly divides the product into two 473 ml solutions for inducing purgation, yet it is indisputable that the FDA would not approve a 473 ml solution for inducing purgation because the safety and efficacy of such a product have never been evaluated. *See* 21 U.S.C. § 355(d)(1).

That "purgation" is the mechanism by which the approved indication of colon cleansing is achieved does not rescue Braintree's argument. Under *Bayer Schering*, whether a drug has certain effects when administered according to the approved label is *irrelevant* if the drug is not FDA-approved for the claimed use. 676 F.3d at 1324 (dismissing fact that drug at issue actually caused the three simultaneous effects claimed by method patent because "the label, taken in its entirety, fails to recommend or suggest to a physician that [the drug] is safe and effective for inducing the claimed combination of effects in patients in need thereof"). It is irrelevant to this motion whether one 473 ml bottle of the ANDA Product induces purgation, because the FDA-approved label requires administration of a full 946 ml—well outside the claimed volume. Using one bottle to achieve something other than colon cleansing is a non-approved use that cannot support a finding of infringement. *Bayer Schering*, 676 F.3d at 1326.

B. Failure to View Breckenridge's ANDA Product as a Whole Renders the "About 100 ml to About 500 ml" Claim Limitation Meaningless

Braintree's claim that the Breckenridge ANDA Product can be viewed as two separate compositions that each meet the "about 100 ml to about 500 ml" limitation is tantamount to arguing that a 0.6 mg capsule infringes a claim requiring no more than a 0.3 mg dosage because,

as the capsule dissolves, the patient initially (and necessarily) ingests less than 0.3 mg of drug. This novel approach to patent infringement would render meaningless the express limitation on the total volume of ingested solution. *See Takeda Pharms. U.S.A., Inc. v. West-Ward Pharm. Corp.*, 785 F.3d 625, 634-35 (Fed. Cir. 2015) (affirming finding of no likely infringement where accused product was a 0.6 mg capsule but claim required 0.3 mg/day dose); *Jeneric/Pentron, Inc. v. Dillon Co.*, 205 F.3d 1377, 1382-83 (Fed. Cir. 2000) (rejecting patentee's attempt to "carve out a portion" of the accused product because it would "read out . . . the express claim ranges").

Braintree attempts to distinguish *Jeneric/Pentron* by arguing that the presence of a functional limitation *somewhere in the claim* alters the unambiguous requirement that the composition comprise "from about 100 ml to about 500 ml of an aqueous solution." That attempt fails because, unlike *Dow Chemical* cited by Braintree, the claims of the '149 patent do ***not*** recite a composition "containing about 100 to about 500 ml of solution for inducing purgation" plus other components for some other purpose. *See infra* Part C; c*f. Dow Chem. Co. v. Nova Chems. Corp.*, 629 F. Supp. 2d 397, 408 (D. Del. 2009). Braintree admits its theory would divide Breckenridge's ANDA Product into one portion "for inducing purgation" and a second portion that also "induces purgation." *See* Opp. at 20. This illustrates the strain in Braintree's attempt to carve out a portion of the ANDA Product: unlike in *Dow Chemical*, there is no limitation in the claims that provides a reason to distinguish one portion of Breckenridge's product from another.

Further, while Braintree accuses Breckenridge of "mischaracterizing" its ANDA Product by stating that it will be administered as 946 ml of aqueous solution without emphasizing that this volume of solution is consumed in two administrations separated by 10-12 hours (*see* MSJ at 1, 19; Opp. at 17; *cf.* MF ¶¶12, 14-17; SF33-35), Braintree itself has repeatedly represented to the USPTO that the volume of ***both*** bottles is relevant to its patent claims. To convince the

USPTO that SUPREP allegedly ***met the volume limitation*** of the original claims of the '149 patent, Braintree stated that the volume of SUPREP is "0.94L." *See* MSJ at 11-12; Dkt. 86-13 at 11; MF ¶¶4-5, 39.[4] Braintree's admission is consistent with how the '149 patent describes the volume of experimental solutions administered in a similar split-dose regimen. Each of the six examples and the comparator are described in terms of the ***total volume*** of two doses that were administered ***10 hours apart***. Dkt. 86-4 at 5:56-6:3; *see infra* Part C.

The claims of the '149 patent do not include any limitation requiring the composition to be ingested without a time separation, so Braintree's focus on the "*separate* 473 ml administrations" is unsupported. Opp. at 17. Indeed, as Dr. Cleveland explains, a split-dose regimen was contemplated from the beginning of development. Dkt. 92, at ¶8. It is the total administered volume, not the timing of ingestion, which is relevant to the infringement inquiry.

Finding infringement based on a single bottle of Breckenridge's ANDA Product would render meaningless the "about 100 ml to about 500 ml" limitation expressly recited in every claim. If a single bottle of the ANDA Product can be found to infringe, so would the prior art compositions administered in multiple 8 oz (273 ml) servings that Braintree distinguished in its specification and during prosecution. *See* Dkt. 86-4 at 1:53-56; MF ¶¶23-31. The Federal Circuit consistently rejects patentees' attempts to ignore portions of an accused product where doing so would "wipe out [an] express limitation" of the claims. *Apple Inc. v. Samsung Elecs. Co.*, 695 F.3d 1370, 1379 (Fed. Cir. 2012); *see also Accent Packaging, Inc. v. Leggett & Platt, Inc.*, 707 F.3d 1318, 1327 (Fed. Cir. 2013). That is just what Braintree is asking this Court to do.

[4] Braintree offers no substantive reason why this admission should not be binding upon it, but, rather, attempts to downplay its significance by stating that it was a "mistake." *See* Opp. at 16 n.17. Even in its Supplemental Request for Patent Term Extension entered to correct the "mistake," however, Braintree asserts that the volume of SUPREP meets the amended volume claim limitation based on the *combined undiluted volume of **both** bottles*. Dkt. 86-14 at 12 ("The approved SUPREP Bowel Prep Kit comprises from about 100 ml to about 500 ml volume of solution. Specifically, the product contains 2 x 6 ounce solutions (*i.e.*, approximately 2 x 0.177 L = .354 L of solution) . . . .").

C. Braintree's Litigation-Inspired Claim Interpretation is Contrary to the Plain Meaning of the Claim Language and the Intrinsic Evidence, Both of Which Require a Total Ingested Volume of "About 100 ml to About 500 ml"

Braintree strives to make this case about the same issue on which it prevailed in the *Novel Case* by improperly tying the volume limitation to the independent "inducing purgation" limitation, and by suggesting that Breckenridge seeks to import a "cleansing" limitation into the claims. But Breckenridge does *not* argue that the 100 to 500 ml composition of the claims must achieve colon cleansing. Rather Breckenridge has shown that the prosecution history and the specification demonstrate that the claimed volume limitation refers to the ***total volume ingested during the treatment period*** (regardless of the ultimate purpose for which the composition is administered). This is the plain meaning of the claim language (a "composition comprising from about 100 ml to about 500 ml") and it is how a person of skill in the art would understand the claims based on their plain language, the specification, and the prosecution history.[5] *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005) (*en banc*).

As a preliminary matter, Braintree suggests that it is improper for Breckenridge to elucidate the scope and meaning of the volume limitation as part of the infringement analysis. This assertion is contrary to the very case law Braintree cites. *See* Opp. at 13-14. Every "determination of infringement requires a two-step analysis" in which the court first "determines the scope and meaning of the patent claims asserted, and then the properly construed claims are compared to the allegedly infringing device." *Abraxis Biosci., Inc. v. Mayne Pharma Inc.*, 467 F.3d 1370, 1375 (Fed. Cir. 2006). Breckenridge did not agree to ignore the requirement of the case law and forgo an explanation of the volume limitation as part of its summary judgment

[5] Braintree misleadingly suggests that the Federal Circuit indicated in the *Novel Case* that the specification and file history should be disregarded. *See* Opp. at 15-16. That is not what the court did. Instead, the Federal Circuit rejected specific arguments by Novel regarding the construction of "purgation" which are irrelevant to Breckenridge's motion. *See Braintree*, 749 F.3d at 1354-55.

motion. Instead, Breckenridge stipulated that it was unnecessary for this Court to construe "purgation" in order to decide this motion. Dkt. 41, at ¶5; *see also* Dkt. 93-1, at 11 ("our view is no matter how you construe purgation, and we disagree with [Braintree's] proposed construction, and we disagree with what Judge Sheridan did, our view is that even if purgation is construed in the manner that they propose, we still win."). As to the claim term "about 100 ml to about 500 ml," Braintree's proposed approach is untenable for several reasons.

First, the plain language of the claim reveals that the phrase "for inducing purgation" is independent and does not redefine the meaning of "about 100 ml to about 500 ml."[6] Braintree asks this Court to re-write claims 15 and 18 to require "a composition of about 100 ml to about 500 ml 'for inducing purgation.'" *See, e.g.*, Opp. at 8; BMF11. Braintree reorders the phrases to make it appear that the composition need only contain 100 ml to 500 ml of solution that functions to induce purgation, allowing for additional volume that induces additional purgation. *See* Opp. at 20. This is contrary to the claim language, which recites "a composition for inducing purgation of the colon of a patient, the composition comprising from about 100 ml to about 500 ml." Claims 15 and 18 thus *separately* require that 1) the composition functions to "induce purgation" and 2) the total administered volume of the composition is about 100 to 500 ml.

Braintree argues that Breckenridge's plain-language interpretation of the claims "ignore[s]" or renders meaningless the "inducing purgation" limitation. Opp. at 14-15. Not so. An infringing composition must "induce purgation" (but does not need to result in complete

[6] The introductory phrase "[a] composition for inducing purgation of the colon of a patient" in composition claims 15 and 18 is known in patent law as a "preamble." *See Catalina Mktg. Int'l. v. Coolsavings.com, Inc.*, 289 F.3d 801, 809 (Fed. Cir. 2002). Such "preambles describing the use of an invention generally do not limit the claims because the patentability of apparatus or composition claims depends on the claimed structure, not on the use or purpose of that structure." *Id.* Here, the Federal Circuit's construction of "purgation" in no way suggests that the preamble phrase requiring a certain use for the invention alters the meaning of the volume limitation. Indeed, Judge Sheridan's claim construction order *never addressed* the 100 ml to 500 ml volume limitation, nor did the Federal Circuit majority interpret it. *See* Dkt. 93-8 at 11; *See Braintree*, 749 F.3d at 1352-61.

"cleansing" of the colon). Breckenridge stipulated that that its product "induces colonic purgation" and therefore meets this limitation. SF37. This does not resolve the question of infringement, however, because the Breckenridge product does not meet the independent limitation requiring a composition volume of "about 100 ml to about 500 ml." *See* MSJ at 18.

Second, the specification makes clear that the "about 100 ml to about 500 ml" limitation refers to the ***total*** volume of solution ingested by a patient during the treatment period. *See* MSJ at 7-10. The specification—which Braintree has asked this Court to disregard as "irrelevant," MF ¶¶19-22—"is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term." *Phillips*, 415 F.3d at 1315 (quotation omitted). Here, ***every single example*** disclosed in the '149 patent was administered in a split-dose regimen like that required by the proposed label for Breckenridge's ANDA Product. Dkt. 86-4, at 5:32-6:3. The specification describes the "volume" of a composition administered in two doses of 165 ml each, given 10 hours apart, as "330 ml"—the ***total volume ingested by the patient***. *Id.* at 5:57-6:3. Moreover, the specification distinguishes the invention from undesirable prior art solutions that were ingested in multiple administrations of 8 oz (273 ml) for a ***total volume*** of one gallon. *Id.* at 1:53-56.

Third, the prosecution history teaches that "about 100 ml to about 500 ml" refers to the total volume of solution ingested. Braintree consistently distinguished the prior art during prosecution on the basis of the ***total volume ingested by the patient***, making no reference to the volume of a "single administration" nor to any minimum amount required to "induce purgation." *See* MSJ 9-10; MF ¶¶23-31; *Braintree*, 749 F.3d at 1364 (J. Dyk, dissenting). And, Braintree told the USPTO that the volume of SUPREP—which Braintree admits is identical in volume and dosing regimen to Breckenridge's ANDA Product—is "0.94L" for purposes of meeting the

volume limitation of the claims. *See* MSJ at 11; Dkt. 86-13 at 11; MF ¶¶4-5, 39. The patent prosecution process serves to put the public on notice as to the scope of a patentee's claims. *Digital Biometrics v. Identix, Inc.*, 149 F.3d 1335, 1347-48 (Fed. Cir. 1998). As a result, Breckenridge is permitted to rely on the written record and the representations Braintree made during prosecution, to determine the proper claim scope. *Id.*; *see also Southwall Techs., Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1576 (Fed. Cir. 1995) ("Claims may not be construed one way in order to obtain their allowance and in a different way against accused infringers.").

Braintree also re-writes claim 23 to claim infringement. Claim 23 does *not* require the effective amount of the composition to be administered "*two or more times* within a treatment period." *Cf.* Opp. at 12 n.11. The claim requires that the effective amount is administered "*in two or more doses* within a treatment period." Dkt. 86-4, at 14:17. This language must be understood in the context of the specification. *Phillips*, 415 F.3d at 1415. In context, claim 23 clearly refers to *dividing* the effective amount into separate administrations. Dkt. 86-4, at 5:19-24 ("Optimally, *the effective dose may be divided* and administered, to the patient *in two, or more administrations* over an appropriate time period."). The conclusory opinion of Braintree's expert, Dr. Puera, gives no reason why a gastroenterologist would understand claim 23 to refer to administering the "effective amount" twice rather than *dividing the effective amount into two administrations* as expressly provided by the specification. Dkt. 91, ¶¶73-77; *Phillips*, 415 F.3d at 1318 ("a court should discount any expert testimony that is clearly at odds with the claim construction mandated by the claims themselves, the written description, and the prosecution history").

III. CONCLUSION

For the reasons set forth in Breckenridge's initial brief and the reasons set forth above, Breckenridge's motion for summary judgment of noninfringement should be granted.

Dated: 07/26/2015

/s/Steven Lieberman
Steven Lieberman
Lisa N. Phillips (Admitted *Pro Hac Vice*)
Jennifer P. Nock (Admitted *Pro Hac Vice*)
ROTHWELL, FIGG, ERNST & MANBECK, P.C.
607 14th Street, N.W., Suite 800
Washington, D.C. 20005
Telephone: (202) 783-6040
Facsimile: (202) 783-6031
slieberman@rfem.com
lphillips@rfem.com
jnock@rfem.com

Attorneys for Defendant
Breckenridge Pharmaceutical, Inc.

CERTIFICATE OF SERVICE

I hereby certify that on July 27, 2015, a true and correct copy of the foregoing DEFENDANT BRECKENRIDGE PHARMACEUTICAL, INC.'S REPLY TO PLAINTIFF BRAINTREE LABORATORIES, INC.'S OPPOSITION TO MOTION FOR SUMMARY JUDGMENT OF NONINFRINGEMENT was filed through the Court's Electronic Filing System (ECF), and was served electronically to the registered participants as identified on the Notice of Electronic Filing (NEF).

/s/ Nasri V. B. Hage
Nasri V. B. Hage
Rothwell Figg Ernst & Manbeck, P.C.